

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Application of: Katherine GALVIN *et al.*

Application No.: To Be Assigned

Group Art Unit: To Be Assigned

Filed: Concurrently Herewith

Examiner: To Be Assigned

For: COMPOSITIONS AND METHODS
FOR TREATMENT AND
DIAGNOSIS OF
CARDIOVASCULAR DISEASE

Attorney Docket No.: 7853-233-999

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
BOX PATENT APPLICATION
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 to inform the Patent Office of all references coming to the attention of Applicants or attorneys or agents for Applicants which are or may be material to the patentability of any claim of the subject application, Attorneys for Applicants hereby direct the Examiner's attention to the references (AA-EZ) listed on the enclosed revised form PTO-1449 entitled "List of References Cited by Applicant."

The above-captioned application is a continuation of Application No. 09/288,292, filed April 8, 1999, which is a continuation-in-part of Application Serial No. 08/870,434, filed June 6, 1997, which is a continuation-in-part of co-pending Application Serial No. 08/799,910, filed February 13, 1997, which claims priority benefit under 35 U.S.C. §119(e) of provisional Application Serial No. 60/011,787, filed February 16, 1996; and this application is a continuation-in-part of Application Serial No. 08/485,573, filed June 7, 1995, which is a continuation-in-part of co-pending Application Serial No. 08/386,844, filed February 10, 1995. Pursuant to 37 C.F.R. §1.98(d), the Examiner is directed to the file of these applications for copies of the references which were cited either by the Applicants in an

Information Disclosure or by the Examiner in connection with an Office Action. However, if the Examiner would prefer, copies of the identified references will be provided.

Identification of the foregoing references is not to be construed as an admission by Applicants or by Attorneys for Applicants that such references are available as "prior art" against the instant application.

Applicants respectfully request that the Examiner review the references and make them of record by completing and returning the enclosed List of References.

No fee is believed due for this submission is being made before the mailing date of the first office action on the merits. Should any fee be required, however, please charge such fee to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

Date February 8, 2002

 39,445

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Enclosure

LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

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U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	5,202,420	04/13/1993	Zasloff et al.	530		
	AB	5,262,311	11/16/1993	Liang et al.	435		
	AC	5,418,162	05/23/1995	Blakely et al.	435		
	AD	5,422,262	06/06/1995	Anderson et al.	435		
	AE	5,424,187	06/13/1995	Shor et al.	435		
	AF	5,545,569	08/13/1996	Grainger et al.	436		
	AG	5,834,248	11/10/1998	Dean A. Falb	435		
	AH	6,054,558	04/25/00	Dean A. Falb	530		
	AI	6,225,084	05/01/01	Dean A. Falb	435		

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AJ	EP 0 282 899 A2	09/21/1988	EPO				
	AK	EP 0 670 369 A2	09/06/1995	EPO				
	AL	WO 95/23858	09/08/1995	PCT				

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	AM	Afrakhte et al., 1998, <i>Biochem. Biophys. Res. Commun.</i> 249 , 505-511
	AN	Barnes et al., 1994, "PCR amplification of up to 35-kb DNA with high fidelity and high yield from λ bacteriophage templates", <i>PNAS USA</i> 91 :2216-2220.
	AO	Bartel et al., 1993, "Using the two-hybrid system to detect protein-protein interactions", <i>Cellular Interactions in Dev. Chap.7</i> , pp. 153-159.
	AP	Bevilacqua et al., 1989, "Endothelial leukocyte adhesion molecule 1: an inducible receptor for neutrophils related to complement regulatory proteins and lectins", <i>Science</i> 243 :1160-1165.
	AQ	Bevilacqua et al., 1991, "Selectins: A family of adhesion receptors", <i>Cell</i> 67 :233.
	AR	Bird et al., 1988, "Single-chain antigen-binding proteins", <i>Science</i> 242 :423-426.
	AS	Blachly-Dyson et al., 1993, "Cloning and functional expression in yeast of two human isoforms of the outer mitochondrial membrane channel, the voltage-dependent anion channel", <i>J. Biol. Chem.</i> 268 :1835-1841.
	AT	Black et al., 1994, "Raloxifene (LY139481 HCl) prevents bone loss and reduces serum cholesterol without causing uterine hypertrophy in ovariectomized rats", <i>J. Clin. Invest.</i> 93 :63-69.

EXAMINER

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OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)			
	AU	Boise et al., 1993, " <i>bcl-x</i> , a <i>bcl-2</i> -related gene that functions as a dominant regulator of apoptotic cell death", <i>Cell</i> 74 :597-608.	
	AV	Boon et al., 1997, <i>Heart</i> 78(5) :472-474	
	AW	Border & Noble, 1995, "Targeting TGF- β for treatment of disease", <i>Nature Med.</i> 1 :1000-1001.	
	AX	Boyer et al., 1999, <i>Dev. Dyn.</i> 214 :81-91	
	AY	Bradley et al., 1992, <i>Biotechnology</i> , Vol. 10, pages 534-539.	
	AZ	Cercek et al., 1990, "Induction of insulin-like growth factor I messenger RNA in rat aorta after balloon denudation", <i>Cir. Res.</i> 66 :1755-1760.	
	BA	Charles et al., 1993, "Genomic structure, cDNA sequence, and expression of <i>gly96</i> , a growth factor-inducible immediate-early gene encoding a short-lived glycosylated protein", <i>Oncogene</i> 8 :797-801.	
	BB	Chen et al., 1996, "A transcriptional partner for MAD proteins in TGF- β signaling", <i>Nature</i> 383 :691-696.	
	BC	Cheng et al., 1994, "Effective amplification of long targets from cloned inserts and human genomic DNA", <i>PNAS USA</i> 91 :5695-5699.	
	BD	Cleary et al., 1986, "Cloning and structural analysis of cDNAs for <i>bcl-2</i> and a hybrid <i>bcl-2</i> /immunoglobulin transcript resulting from the t(14;18) translocation", <i>Cell</i> 47 :19-28.	
	BE	Coffman et al., 1990, " <i>Xotch</i> , the <i>Xenopus</i> homolog of <i>Drosophila Notch</i> ", <i>Science</i> 249 :1438-1441.	
	BF	A. Coghlan, 1995, "Gene dream fades away", <i>New Scientist</i> :14-15	
	BG	Cohen et al., 1988, <i>J. Pharmacol. Exp. Ther.</i> 244 : 550-555	
	BH	Coffman et al., 1990, " <i>Xotch</i> , the <i>Xenopus</i> homolog of <i>Drosophila Notch</i> ", <i>Science</i> 249 :1438-1441.	
	BI	Cybulsky & Gimbrone, 1991, "Endothelial expression of a mononuclear leukocyte adhesion molecule during atherogenesis", <i>Science</i> 251 :788-791.	
	BJ	Davies et al., 1986, "Turbulent fluid shear stress induces vascular endothelial cell turnover <i>in vitro</i> ", <i>PNAS USA</i> 83 :2114-2117.	
	BK	Diamond et al., 1993, "Novel delayed-early and highly insulin-induced growth response genes", <i>J. Biol. Chem.</i> 268 :15185-15192.	
	BL	Ebert et al., 1988, <i>Molecular Endocrinology</i> , Vol. 2, pages 277-283.	
	BM	Eisenberg et al., 1995, <i>Circ. Res.</i> 77 :1-6	
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BN	Eppert et al., 1996, "MADR2 maps to 18q21 and encodes a TGF β -regulated MAD-related protein that is functionally mutated in colorectal carcinoma", <i>Cell</i> 86 :543-552.		
BO	Farrow et al., 1995, "Cloning of a <i>bcl-2</i> homologue by interaction with adenovirus E1B 19K", <i>Nature</i> 374 :731-733.		
BP	Fuller et al., 1996, "Genetic Engineering of Cardiac Muscle Cells: In Vitro and In Vivo", <i>Seminars in Oncology</i> , 23 :4-21.		
BQ	M.A. Gimbrone, 1976, "Culture of vascular endothelium", <i>Progress in Hemostasis and Thrombosis</i> Spaet (ed.), Grune & Stratton Inc., NY, 3 :1-28.		
BR	Grainger et al., 1993, "Proliferation of human smooth muscle cells promoted by lipoprotein(a)", <i>Science</i> 260 :1655-1658.		
BS	Grainger et al., 1995, "Tamoxifen elevates transforming growth factor- β and suppresses diet-induced formation of lipid lesions in mouse aorta", <i>Nature Med.</i> 1 :1067-1073.		
BT	Gromadzinska & Sklodowska, 1990, "Erythrocyte glutathione peroxidase and myocardial infarction", <i>JAMA</i> 263 :949-950.		
BU	Guidi et al., 1986, "Platelet glutathione peroxidase activity is impaired in patients with coronary heart disease", <i>Scand. J. Clin. Lab Invest.</i> 46 :549-551.		
BV	T. Gura et al., 1995, "Estrogen: Key player in heart disease among women", <i>Science</i> 269 :771-773.		
BW	Hata et al., 1998, <i>Genes Dev.</i> 12 :186-197.		
BX	Hakes & Berezney, 1991, "Molecular cloning of matrix F/G: A DNA binding protein of the nuclear matrix that contains putative zinc finger motifs", <i>PNAS USA</i> 88 :6186-6190.		
BY	K. Heckl, 1988, "Isolation of cDNAs encoding human manganese superoxide dismutase", <i>Nuc. Acids Res.</i> 16 :6224.		
BZ	Hockenbery et al., 1993, "Bcl-2 functions in an antioxidant pathway to prevent apoptosis", <i>Cell</i> 75 :241-251.		
CA	Hochman et al., 1995, "Dissociation of synchronization and excitability in furosemide blockage of epileptiform activity", <i>Science</i> 270 :99-102.		
CB	Hoodless et al., 1996, "MADR1, a MAD-related protein that functions in BMP2 signaling pathways", <i>Cell</i> 85 :489-500.		
CC	Huang et al., 1995, <i>Ann. N.Y. Acad. Sci.</i> 752 :317-330.		
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	CD	Imamura et al., 1997, <i>Nature</i> 389 :622-626.	
	CE	Jones et al., 1993, "Molecular cloning of human prostaglandin endoperoxide synthase type II and demonstration of expression in response to cytokines", <i>J. Biol. Chem.</i> 268 :9049-9054.	
	CF	Karttinen et al., 1995, <i>Nat. Genet.</i> 11 :415-421.	
	CG	Kanai et al., 1995, "Identification and characterization of a prostaglandin transporter", <i>Science</i> 268 :866-869.	
	CH	Kita et al., 1987, "Probucol prevents the progression of atherosclerosis in Watanabe heritable hyperlipidemic rabbit, and animal model for familial hypercholesterolemia", <i>PNAS USA</i> 84 :5928-5931.	
	CI	Kojima et al., 1991, "Lipoprotein (a) inhibits the generation of transforming growth factor β : An endogenous inhibitor of smooth muscle cell migration", <i>J. Cell Biol.</i> 113 :1439-1445.	
	CJ	Kok et al., 1989, "Decreased selenium levels in acute myocardial infarction", <i>JAMA</i> 261 :1161-1164.	
	CK	Kondratyev, et al., 1996, "Identification and Characterization of a Radiation-inducible Glycosylated Human Early-Response Gene", <i>Cancer Research</i> 56 :1498-1502.	
	CL	Kumar & Chambon, 1988, "The estrogen receptor binds tightly to its responsive element as a ligand-induced homodimer", <i>Cell</i> 55 :145-156.	
	CM	Kume et al., 1992, "Lysophosphatidylcholine, a component of atherogenic lipoproteins, induces mononuclear leukocyte adhesion molecules in cultured human and rabbit arterial endothelial cells", <i>J. Clin. Invest.</i> 90 :1138-1144.	
	CN	F. Ledley, 1995, "Nonviral gene therapy: The promise of genes as pharmaceutical products", <i>Human Gene Therapy</i> 6 :1129-1144.	
	CO	Li et al., 1991, "Early induction of an atherosclerosis-associated endothelial-leukocyte adhesion molecule (athero-ELAM) by an atherogenic diet in rabbits", <i>Arterioscler. Thromb.</i> 11 :1397a.	
	CP	Li et al., 1998, <i>Hypertension</i> 33 :271-275.	
	CQ	Liew et al., Gene Bank (AN:T20268, D345F Homo sapiens cDNA clone D345, Nov. 28, 1994)	
	CR	Liew et al., "A catalogue of genes in the cardiovascular system as identified by expressed sequence tags" 1994, <i>PNAS</i> , 91 :10645-10649	
	CS	Lindroos et al., 1993, <i>J. Am. Coll. Cardiol.</i> 21 (5):1220-1225	
	CT	Luscinskas et al., 1989, "Endothelial-leukocyte adhesion molecule-1-dependent and leukocyte (CD11/CD18)-dependent mechanisms contribute to polymorphonuclear leukocyte adhesion to cytokine-activated human vascular endothelium", <i>J. Immunol.</i> 142 :2257-2263.	
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	CU	Majesky et al., 1990, "PDGF ligand and receptor gene expression during repair of arterial injury", <i>J. Cell Biol.</i> 111 :2149-2158.	
	CV	Malden et al., 1991, "The influence of oxidatively modified low density lipoproteins on expression of platelet-derived growth factor by human monocyte-derived macrophages", <i>J. Biol. Chem.</i> 266 :13901-13907.	
	CW	Marchuk, D.A., 1998, <i>Curr Opin Hematol</i> 5 :332-338	
	CX	E. Marshall, , "Less hype, more biology needed for gene therapy",	
	CY	E. Marshall, 1995, "Gene therapy's growing pains", <i>Science</i> 269 :1050-1055.	
	CZ	Mastrangelo et al., 1994, "Gene Therapy for Human Cancer: An Essay for Clinicians", 16:17-25.	
	DA	Mohler et al., 1997, <i>Arterioscler. Thromb. Vasc. Biol.</i> 17 (3):547-552	
	DB	Moore et al., 1998, <i>Dev. Dyn.</i> 212 :548-562	
	DC	Mullins et al., 1996, <i>Journal of Clinical Investigation</i> , Vol. 98, No. 11, pages S37-S40.	
	DD	Nagel et al., 1994, "Shear stress selectively upregulates intercellular adhesion molecule-1 expression in cultured human vascular endothelial cells", <i>J. Clin. Invest.</i> 94 :885-891.	
	DE	Nakajima et al., 1998, <i>Dev. Bio.</i> 194 :99-113	
	DF	Navab et al., 1988, "Monocyte migration into the subendothelial space of a coculture of adult human aortic endothelial and smooth muscle cells", <i>J. Clin. Invest.</i> 82 :1853-1863.	
	DG	Ngo et al., 1994, "Computational Complexity, Protein Structure Prediction, and the Levinthal Paradox", <i>The Protein Folding Problem and Tertiary Structure Prediction</i> , Merz et al., (ed.), Birkhauser, Boston, MA pp. 433 and 492-495.	
	DH	Nikol et al., 1992, "Expression of transforming growth factor- β 1 is increased in human vascular restenosis lesions", <i>J. Clin. Invest.</i> 90 :1582-1592.	
	DI	Nomura et al., 1998, <i>Nature</i> 393 :786-790.	
	DJ	Ohno et al., 1994, "Gene therapy for vascular smooth muscle cell proliferation after arterial injury", <i>Science</i> 265 :781-784.	
	DK	Oltvai et al., 1993, "Bcl-2 heterodimerizes in vivo with a conserved homology, Bax, that accelerates programmed cell death", <i>Cell</i> 74 :609-619.	
	DL	Orkin & Motulsky, 1995, "Report and recommendations of the panel to assess the NIH investment in research on gene therapy", <i>NIH Report</i> .	
	DM	Osborn et al., 1989, "Direct expression cloning of vascular cell adhesion molecule 1, a cytokine-induced endothelial protein that binds to lymphocytes", <i>Cell</i> 59 :1203-1211.	
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	DN	Oshima et al., 1996, <i>Dev. Biol.</i> 179 :297-302.	
	DO	Papadaki et al., 1997, Effects of Fluid Shear Stress on Gene Regulation of Vascular Cells", <i>Biotechnol. Prog.</i> 13 :209-221.	
	DP	Patrick Jr., et al., 1995, "Shear stress and cyclic strain modulation of gene expression in vascular endothelial cells", <i>Blood Purification</i> 13 :112-124.	
	DQ	Perrella et al., 1998, <i>Miner Electrolyte Metab</i> 24 :136-143.	
	DR	Plump et al., 1992, "Severe hypercholesterolemia and atherosclerosis in apolipoprotein e-deficient mice created by homologous recombination in ES cells", <i>Cell</i> 71 :343-353.	
	DS	Porter et al., 1992, "Plasma, platelet and erythrocyte glutathione peroxidases as risk factors in ischaemic heart disease in man", <i>Clinical Science</i> 83 :343-345.	
	DT	Poston et al., 1992, "Expression of intercellular adhesion molecule-1 in atherosclerotic plaques", <i>Am. J. Pathol.</i> 140 :665-673.	
	DU	Proetzel et al., 1995, <i>Nat. Genet.</i> 11 :409-414.	
	DV	Puolakkainen et al., 1993, "Serological response to <i>Chlamydia pneumoniae</i> in adults with coronary arterial fatty streaks and fibrolipid plaques", <i>J. of Clinical Microbiol.</i> 31 :2212-2214.	
	DW	Proetzel et al., 1995, <i>Nat. Genet.</i> 11 :409-414.	
	DX	Raftery et al., 1988, "Genetic screens to identify elements of the <i>decapentaplegic</i> signaling pathway in <i>Drosophila</i> ", <i>Genetics</i> 139 :241-254.	
	DY	Ramsdell et al., 1997, <i>Dev. Biol.</i> 188 :64-74.	
	DZ	Rapacz et al., 1986, "Lipoprotein mutations in pigs are associated with elevated plasma cholesterol and atherosclerosis", <i>Science</i> 234 :1573-1577.	
	EA	Resnick et al., 1993, "Platelet-derived growth factor B chain promoter contains a cis-acting fluid shear-stress-responsive element", <i>PNAS USA</i> 90 :4591-4595.	
	EB	R. Ross, 1993, "The pathogenesis of atherosclerosis: A perspective for the 1990s" <i>Nature</i> 362 :801-809.	
	EC	Sambrook et al.(eds), 1989, "Estimating the Effects of Mismatches", <i>Molecular Cloning - A Laboratory Manual</i> 2 nd Edition, pg 11.47.	
	ED	Sanford et al., 1997, <i>Development</i> 124 :2659-2670	
	EE	Schulick et al., 1998, <i>Proc. Natl. Acad. Sci.</i> 95 :6983-6988	
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	EF	Sekelsky et al., 1995, "Genetic characterization and cloning of <i>Mothers against dpp</i> , a gene required for <i>decapentaplegic</i> function in <i>Drosophila melanogaster</i> ", <i>Genetics</i> 139 :1347-1358.	
	EG	Serra & Moses, 1996, "Tumor suppressor genes in the TGF- β signaling pathway?", <i>Nature Med.</i> 2 :390-391.	
	EH	Shreeniwas et al., 1991, "Reoxygenation stimulates IL-1 α production, increasing leukocyte adherence to endothelium via expression of ICAM-1 and ELAM-1", <i>Arterioscler. Council Abstracts</i> 11 :1397a.	
	EI	Shyy et al., 1995, "Multiple cis-elements mediate shear stress-induced gene expression", <i>J. Biomechanics</i> 28 :1451-1457.	
	EJ	Simmons et al., 1988, "ICAM, an adhesion ligand of LFA-1, is homologous to the neural cell adhesion molecule NCAM", <i>Nature</i> 331 :624-627.	
	EK	Speir et al., 1994, "Potential role of human cytomegalovirus and p53 interaction in coronary restenosis", <i>Science</i> 265 :391-394.	
	EL	Takahashi et al., 1990, "Primary structure of human plasma glutathione peroxidase deduced from cDNA sequences", <i>J. Biochem.</i> 108 :145-148.	
	EM	Takase et al., 1998, <i>Biochem. Biophys. Res. Commun.</i> 244 :26-29.	
	EN	Takayama et al., 1995, "Cloning and functional analysis of BAG-1: A novel bcl-2 binding protein with anti-cell death activity", <i>Cell</i> 80 :279-284.	
	EO	Tanaka et al., 1993, "Sustained activation of vascular cells and leukocytes in the rabbit aorta after balloon injury", <i>Circulation</i> 88 :1788-1803.	
	EP	Topper et al., 1997, <i>Proc. Natl. Acad. Sci.</i> 94 :9314-9319.	
	EQ	Tsujimoto et al., 1984, "Cloning of the chromosome breakpoint of neoplastic α cells with the t(14;18) chromosome translocation", <i>Science</i> 226 :1097-1099.	
	ER	Wallace & Miyada, 1987, "Oligonucleotide probes for the screening of recombinant DNA libraries", <i>Methods in Enzymology</i> 152 :432-443.	
		Wall, 1996, <i>Theriogenology</i> , Vol. 45, pages 57-68.	
	ES	Wang et al., 1981, "Selenium and myocardial infarction: Glutathione peroxidase in platelets", <i>Klin. Wochenschr.</i> 59 :817-818.	
	ET	Watson et al., 1994, <i>J. Clin. Invest.</i> 93 :2106-2113	
	EU	Weatherall, D.J., 1995, "Scope and limitations of gene therapy", <i>British Medical Bulletin</i> 51 :1-11.	
	EV	Wieser et al., 1995, "GS domain mutation that constitutively activate T β R-I, the downstream signaling component in the TGF- β receptor complex", <i>EMBO J.</i> 14 :2199-2208.	
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	EW	Wilson et al., 1994, "2.2 Mb of contiguous nucleotide sequence from chromosome III of <i>C. elegans</i> ", <i>Nature</i> 368 :32-38.	
	EX	Wrana et al., 1994, "Mechanism of activation of the TGF- β receptor", <i>Nature</i> 370 :341-347.	
	EY	Xu et al., 1994, "Molecular cloning and functional expression of the bumetanide-sensitive Na-K-Cl cotransporter", <i>PNAS USA</i> 91 :2201-2205.	
	EZ	Yoshimura et al., 1994, "The human plasma glutathione peroxidase-encoding gene: Organization, sequence and localization of chromosome 5q32", <i>Gene</i> 145 :293-297.	
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